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GE Medical Systems
Information Technologies

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8200 West Tower Avenue
Milwaukee, Wisconsin,
53223

APR 15 2009

Section 5: 510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	March 13, 2009
Submitter:	GE Medical Systems *Information Technologies* 8200 West Tower Avenue Milwaukee, Wisconsin 53223
Primary Contact Person:	David Wahlig Regulatory Affairs Director GE Medical Systems *Information Technologies* Telephone: 414-362-3242 Fax: 414-362-2585 E-mail: David.Wahlig@med.ge.com
Secondary Contact Person:	Robert Casarsa Regulatory Affairs Leader GE Medical Systems *Information Technologies* Telephone: 414-362-3063 Fax at 414-362-2585 E-mail: Robert.casarsa@ge.com
Device: Trade Name:	Dash 2500 Patient Monitor
Common/Usual Name:	Physiological Patient Monitor (Multi-parameter Module)
Classification Names:	21 CFR 870.1025 Physiologic Patient Monitor (with arrhythmia detection or alarms)
Product Code:	MHX
Predicate Device:	K080157 Dash 2500 Patient Monitor
Device Description:	The Dash 2500 Patient Monitor is a portable (intra-hospital) multi-parameter monitor designed for monitoring adult, pediatric, and neonate patient vital signs. The Dash 2500 Patient Monitor is self-contained and can be powered by batteries or AC. The Monitor has a carrying handle and can be operated on a shelf or table. It can also be mounted in a variety of ways (e.g., wall, pole, bed rail, or head/foot board) using a mounting plate located on the bottom of the Monitor. The Monitor can be used as a stand-alone monitor with the capability to interface to a central station, a server or any other device capable of receiving data using the host communications protocol.
Intended Use:	The Dash 2500 Patient Monitor is intended for use under the direct supervision of a licensed healthcare practitioner. The intended use of this device is a portable (intra-hospital) multiparameter unit designed for monitoring adult, pediatric, and neonate patient vital signs in a

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hospital subacute care environments, such as same-day surgery, emergency rooms, recovery/PACU, progressive care, interventional radiology, special care units, and GI/endoscopy.

The Dash 2500 Patient Monitor monitors and displays oscillometric non-invasive blood pressure (systolic, diastolic and mean arterial pressure), heart/pulse rate, respiration rate, ECG, temperature with an reusable electronic thermometer (predictive mode for oral and rectal temperature measurement, monitor mode for axillary temperature measurement), and functional oxygen saturation (SpO2) and pulse rate via spot checking and continuous monitoring, including monitoring during conditions of clinical patient motion or low perfusion.

The Dash 2500 Patient Monitor also detects alarm limit conditions and is capable of recording up to two waveforms. Using this monitor a clinician can view, record and recall clinical data derived from each parameter.

Technology: The Dash 2500 Patient Monitor employs the same functional scientific technology as its predicate device.

Determination of Substantial Equivalence: The Dash 2500 Patient Monitor and its applications comply with voluntary standards as detailed in Section 9 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Summary of Clinical Tests:
The subject of this premarket submission, Dash 2500 Patient Monitor, did not require clinical studies to support substantial equivalence.

Conclusion: GE Medical Systems *Information Technologies* considers the Dash 2500 Patient Monitor to be as safe, as effective, and its performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 2009

GE Medical Systems Information Technologies
c/o Mr. David Wahlig
Regulatory Affairs Director
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K090702
Trade/Device Name: Dash 2500 Patient Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (including ST-Segment measurement and alarm)
Regulatory Class: Class II (two)
Product Code: MHX, DXN, DPS, DQA and FFL
Dated: March 16, 2009
Received: March 17, 2009

Dear Mr. Wahlig:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090702

510(k) Number (if known):
Device Name: Dash 2500 Patient Monitor

Indications for Use:

The Dash 2500 Patient Monitor is intended for use under the direct supervision of a licensed healthcare practitioner. The intended use of this device is a portable (intra-hospital) multiparameter unit designed for monitoring adult, pediatric, and neonate patient vital signs in a hospital subacute care environments, such as same-day surgery, emergency rooms, recovery/PACU, progressive care, interventional radiology, special care units, and GI/endoscopy.

The Dash 2500 Patient Monitor monitors and displays oscillometric non-invasive blood pressure (systolic, diastolic and mean arterial pressure), heart/pulse rate, respiration rate, ECG, temperature with an reusable electronic thermometer (predictive mode for oral and rectal temperature measurement, monitor mode for axillary temperature measurement), and functional oxygen saturation (SpO2) and pulse rate via spot checking and continuous monitoring, including monitoring during conditions of clinical patient motion or low perfusion.

The Dash 2500 Patient Monitor also detects alarm limit conditions and is capable of recording up to two waveforms. Using this monitor a clinician can view, record and recall clinical data derived from each parameter.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) 4/14/09
Division of Cardiovascular Devices

510(k) Number K090702